



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,633	03/18/2004	Rajesh R. Naik	3148-6231.1US (UNI 0051 M	8019
24247	7590	04/17/2007	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			MEAH, MOHAMMAD Y	
			ART UNIT	PAPER NUMBER
			1652	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/17/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/803,633	Applicant(s) NAIK ET AL.	
	Examiner Mohammad Meah	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
 4a) Of the above claim(s) is/are withdrawn from consideration.
- 5) ☐ Claim(s) is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☒ Claim(s) 1-18 is/are objected to.
- 8) ☐ Claim(s) are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u> </u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/18/04</u> | 6) <input type="checkbox"/> Other: <u> </u> |

DETAILED ACTION

Claims 1-18 are pending in the instant application.

Election/Restriction

During preliminary amendment of this application, the applicant, on date 01/22/2007 elected without traverse Group I (claims 1-18), drawn to method of immobilizing a compound on silica matrix using silaffin polypeptide comprising SEQ ID NO: 1 for examination. Groups II-VII (Claims 1-4 and 6-18) of election/restriction-office action of date 12/07/2006 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Priority

Acknowledgement is made of applicant's application priority date of 10/31/2003 based on provisional application 60/517227.

Claim Objections

Claims 1-18 are objected to contain non-elected subject matter.
Appropriate correction is required.

Claim Rejections

35 U.S.C 112

35 U.S.C. 112 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1652

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-18 - the recitation "hydroxylated water-soluble derivatives" makes the claim indefinite and vague. As it is unclear what "hydroxylated water-soluble derivatives" term means and what are these derivatives from.

Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form..

Claim 13 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 12. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 13 and 14, therefore, should be cancelled or be modified.

35 U.S.C. 112 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 6-18 are directed to a method of immobilizing **any compound** in silicon matrix using **any hydroxylated water-soluble derivatives** and **any siliffin polypeptide** from any source. Claims 4-5 are directed to process of immobilizing **any compound** on silica matrix using **any hydroxylated water-soluble derivatives** and siliffin polypeptide comprising SEQ ID NOs: 1-7. For the broad generic claims 1-3 and 6-18, since **only silicon compound form silicon matrix** after precipitation by siliffin polypeptide, the specification fails to describe how a siliffin polypeptide can precipitates **any hydroxylated water-soluble derivatives** as said derivatives may or may not silicon compounds and therefore may not precipitated by siliffin polypeptide to form a silica matrix. For the broad generic claims 1-3 and 6-18, the specification fails to describe any

Art Unit: 1652

other representative species of siliffin polypeptide by any identifying characteristics or properties other than precipitating silica by siliffin polypeptide. For claims 1-18, the specification fails to describe in any fashion the physical and/or chemical properties of the claimed class of compounds that are immobilized. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of immobilizing Horse Radish peroxidase or butyrylcholinesterase using siliffin polypeptide of SEQ ID Nos 1-7 and silicic acid to precipitate forming silica matrix, does not reasonably provide enablement for method of immobilizing any compound on silica matrix using any hydroxylated water-soluble derivatives and any siliffin polypeptide. The claims broadly recite the use of **any** substance, which is immobilized on silica matrix using any hydroxylated water-soluble derivatives and any siliffin polypeptide. The specification fails to describe how any compound is immobilized in any silica matrix formed by the precipitation of hydroxylated water-soluble derivative by a siliffin polypeptide and how any siliffin polypeptide can precipitate any hydroxylated water-soluble derivatives to form silica matrix. The specification fails to describe in any fashion the physical and/or chemical properties of compounds that can be immobilized on silica matrix as well as hydroxylated

Art Unit: 1652

water-soluble derivatives that can be precipitated by silaffin polypeptide to form said silica matrix. The physical and/or chemical properties of the compounds that are immobilized and the physical and/or chemical properties of the hydroxylated water-soluble derivatives is important for the precipitation of the later compound by silaffin polypeptide to immobilize the former compound. The shape and bulkiness of the compound, the pore size of the silica matrix as well as interaction between compound and the silica particle are highly critical in immobilizing the compound in the precipitated silica. As the physical and/or chemical properties of the immobilized compound are not defined in any way as well as the physical and/or chemical properties of the hydroxylated water-soluble derivatives, one of ordinary skill in the art would not be able to make and use all such substances without undue experimentation to first find what substances in fact fall within the claimed class. Furthermore, the claimed compounds are likely to include many compounds, which one of ordinary skill in the art would be unable to make and use without undue experimentation, even if it was known or expected that the substance be within the scope of the claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-3, 6-18 are so broad as to encompass any method of immobilizing any compound on silica matrix using any silaffin polypeptide. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to any method of immobilizing any compound on any silica matrix using any silaffin polypeptide by precipitating any hydroxylated water-soluble derivatives broadly encompassed by the claims. In view of the great breaths of claims 1-3, 6-18, amount of experimentation required to precipitate hydroxylated water-soluble derivatives of silica along with any compound by using any silaffin polypeptide and, the lack of guidance, working examples, unpredictability of the art in predicting the function (precipitation of silica) from protein's structure (Whisstock, et al. Quarterly Rev. Biophy. 2003, 36, pp 307-340), the claimed invention would require undue experimentation. As such the specification fail to teach one of ordinary skill how to use the full scope of the claims.

Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the

Art Unit: 1652

disclosure is limited to precipitation of silica by a few siliffin polypeptides. (SEQ ID NO: 1-6).

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass any method of immobilizing any compound on silica matrix using any siliffin polypeptide because the specification does not establish: (A) regions of the protein structure which may be modified to precipitate silica (B) the general tolerance of modification and extent of such tolerance on siliffin activity; (C) a rational and predictable scheme for modifying any siliffin polypeptide amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any method of immobilizing any compound on silica matrix using any siliffin polypeptide. The

Art Unit: 1652

scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of oxidoreductase variants, having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir,1988).

CLAIM Rejection - 35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-8, 10-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Mcauliffe et al.(US 20040039179). Mcauliffe et al. teach methods of forming composite material of silica wherein inclusion of enzyme, polar compound or other polypeptides is occurred in silica when various silicon compounds including silicic acid (a hydroxylated water soluble silica derivative) is precipitated (in presence of above-mentioned compound) by various siliffin polypeptides wherein siliffin polypeptide of SEQ ID NO: 1 of Mcauliffe et al. has 100% sequence identity with the SEQ ID NO: 1 of the instant application.

Mcauliffe et al. also teach the method of forming composite material of silica at

Art Unit: 1652

pH 5-10, at variety temperatures, including at 25 °C and the immobilized peptide (which include enzymes such as beta lactamase) also comprise metal chelate attached to magnetic particle.

Conclusion

Claims 1-18 are rejected and no claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1652

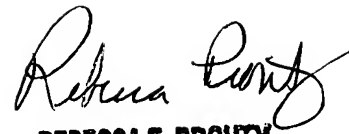
Mohammad Younus Meah, PhD

Examiner, Art Unit 1652

Recombinant Enzymes, 3C31 Remsen Bld

400 Dulany Street, Alexandria, VA 22314

Telephone: 517-272-1261


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1652